



510(k) Summary in accordance with 21CFR 807.92. Assigned 510(k) number is **K113795**

AUG 7 2012

Traditional 510(k) Submission by:

Black & Black Surgical, Inc.

5238 Royal Woods Parkway

Suite 170

Tucker, GA 30084 USA

770-414-4880

**Contact Person:**

Norman M. Black III

CEO, Black & Black Surgical Inc.

770-414-1813

**Date Prepared:** June 29, 2012

**Establishment Registration Number:** 3006142527

**Suction Lipoplasty System** 21 CFR 878.5040 (05 Jan 1998)  
Manual Surgical Instruments for General Use  
21 CFR 878.4800 (1994)

**Common Usual Name:** Aspiration and infiltration Cannulae/Needles

**Proprietary Name:** ~ Lipoplasty/Liposuction Aspiration and  
Tumescent Infiltration Cannulae/Needles  
(Cannulae and Needles)

**Classification Name:** Class II, 21 CFR 878.5040, Suction Lipoplasty System, Panel  
79, MUU, General and Plastic Surgery

**Predicate Device:** **Suction Cannulae and Needles**  
Manufacturer: Byron Medical, Inc.  
510(k) Number: K981172  
Substantially Equivalence Date: June 30, 1998

**Device Description:** Black and Black Surgical Cannulae and Needles are used to remove fluid, soft tissue, and exudates and infusion, utilizing a hollow stainless steel tube and multiple tips, handle and attachment connectors that are in reusable and disposable configuration. They are used during general, plastic, and reconstructive procedures.

**Device Description Chart**

Description*	Product Code	Length	Features	Packaging
Cannulae & Needles	B8- AAA— B8-ZZZ	Various	Straight	1 each

Black and Black Surgical Cannulae and Needles are manufactured of stainless steel tubes, with Aluminum Handles.

The patient contacting material in Black and Black Surgical Cannulae and Needles is stainless steel.

**Indication for Use:** The aspiration and infusion cannulae and needles indications are for aesthetic body contouring and general tissue aspiration.

**Shared Technical Characteristics with Predicate Device:**

The Black and Black Surgical Cannulae and Needles are substantially equivalent in function and intended use to the Byron Suction Cannulae and Needles (K981172). Both devices are used for aesthetic body contouring and general tissue aspiration by means of aspiration and infiltration which the FDA has found to be substantially equivalent to these devices in accordance with Section 878.5040 Suction Lipoplasty System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

AUG 7 2012

Black and Black Surgical, Incorporated  
% Mr. Norman M. Black III  
Chief Executive Officer  
2759 Hawthorne Drive, Northeast  
Atlanta, Georgia 30345

Re: K113795

Trade/Device Name: Liposuction Aspiration and Tumescant Infiltration Cannulae and  
Needles

Regulation Number: 21 CFR 878.5040

Regulation Name: Suction lipoplasty system

Regulatory Class: Class II

Product Code: MUU, GEA

Dated: June 29, 2011

Received: July 05, 2011

Dear Mr. Black III:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

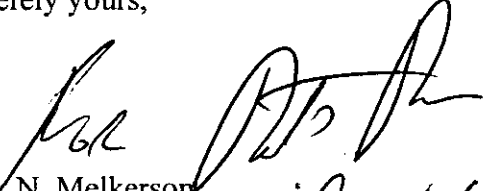
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

*Dec 11 11:00 AM*

Enclosure

## Indications for Use

510(k) Number: K113795

Device Name: Liposuction Aspiration and Tumescant Infiltration Cannulae and Needles

### Indications for Use:

The aspiration and infusion cannulae and needles are indicated for aesthetic body contouring and general tissue aspiration.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

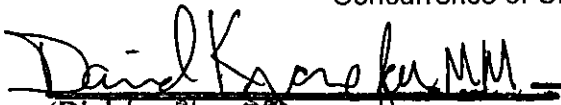
AND/OR

Over-The Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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